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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/123,253	07/27/1998	T. WILLIAM HUTCHENS	D-5639-C4	5339

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EXAMINER

ALEXANDER, LYLE

ART UNIT PAPER NUMBER

1743

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/123,253

Applicant(s)

HUTCHENS ET AL.

Examiner

Lyle A Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 35, 51, 88 and 89 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7/2/04.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continuation of Disposition of Claims: Claims pending in the application are 49-53,56,57,60,61,63-71,75,76,82,87-91,94,95,104-113,120-127,130-141 and 144-148.

Continuation of Disposition of Claims: Claims rejected are 49,50,52,56,57,60,61,63-71,75,76,82,87,90,91,94,95,104-113,120-127,130-141 and 144-148.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 49, 64, 67-71, 86, 126-127 and 136 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Westlake et al. (USP 5,317,932).

The invention is best understood in light of the above 35 USC 112 issues, a single probe is used to collect the sample. Westlake et al. in column 2 lines 10-17 characterize Brodbelt et al. as teaching a mass spectrometric determination of in vivo analytes by use of a single nylon sample probe.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 49-50, 52, 56-57, 63-67, 69-71, 75-76, 82, 86-87, 90-91, 94-95, 101, 105-113, 120-127, 130-134, 137-141 and 144-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 3221681 (note the attached translation of the document).

As the invention is best understood in light of the above 35 USC 112 issues, a single probe is used to collect the sample. DE 3221681 teaches a method and apparatus for using a laser to desorb a biological sample from a polymer film further subjecting the desorbed sample on a single probe to subsequent mass spectrometry analysis.

DE 3221681 is silent to the type of polymer used and if the material is open or closed pore.

The court decided In re Leshin (125 USPQ 416) that mere selection of known plastic being on the basis of suitability for the intended use would be entirely obvious. The claimed polystyrene, polypropylene, polycarbonate, nylon and dextran as well as the porosity of these polymers are all well known polymeric materials in the art commonly used in biological assays because of inertness, light weight, high strength, low cost of manufacture and ease of disposal (e.g. all these materials can be readily incinerated). Open pores are advantageous better retain the sample while closed pores have the advantage of leaving more of the sample available to analysis.

It would have been within the skill of the art to modify DE 3221681 and use polymeric materials such as polystyrene, polypropylene, polycarbonate, nylon and dextran as well as selecting the relative porosity (e.g. open/closed pores) to gain the above advantages and as selection of a material based upon its suitability of intended use.

Claims 49, 64, 65-71, 80, 86, 126-127, 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami.

Cerami teaches in column 11 lines 48+ a mass spectrometry apparatus using a ceramic probe tip to present the sample.

Cerami is silent to the polymer used and if the material is open or closed pore.

The court decided In re Leshin (125 USPQ 416) that mere selection of known plastic being on the basis of suitability for the intended use would be entirely obvious. The claimed polystyrene, polypropylene, polycarbonate, nylon and dextran as well as the porosity of these polymers are all well known polymeric materials in the art

commonly used in biological assays because of inertness, light weight, high strength, low cost of manufacture and ease of disposal (e.g. all these materials can be readily incinerated). Open pores are advantageous better retain the sample while closed pores have the advantage of leaving more of the sample available to analysis.

It would have been within the skill of the art to modify Cerami and use polymeric materials such as polystyrene, polypropylene, polycarbonate, nylon and dextran as well as selecting the relative porosity (e.g. open/closed pores) to gain the above advantages and as selection of a material based upon its suitability of intended use.

Claims 50,52,56-57,60-61,63,75-76,82,87-91,94-95, 101,104-113,120-125, 130-134, 137-141 and 144-149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami or Westlake et al. in view of Stuke (USP 4,686,366).

See Cerami and Westlake et al. *supra*.

Cerami and Westlake et al. are silent to the claimed use of laser desorption of the sample, the use of glass and their relative porosity (e.g. open/closed pore) of either the taught ceramic or glass.

Stuke teaches in column 1 lines 37+ that mass spectrometry analysis may fragment samples. It is advantageous to use a laser to desorb the sample to supply the mass spectrometer with large intact analytes.

It would have been within the skill of the art to modify Cerami or Westlake et al. in view of Stuke and use a laser to desorb the samples to gain the above advantages.

The court decided In re Leshin (125 USPQ 416) that mere selection of known materials being on the basis of suitability for the intended use would be entirely obvious.

Cerami teaches use of a ceramic material which is silicon based . It would have been within the skill of the art to use other well known silicon based materials such as glass. Glass as well as its relative porosity is a well known in the art as commonly used in biological assays because of inertness, light weight, high strength, low cost of manufacture and ease of disposal (e.g. all these materials can be readily incinerated). Open pores are advantageous better retain the sample while closed pores have the advantage of leaving more of the sample available to analysis.

It would have been within the skill of the art to modify Cerami or Westlake et al. in view of Stuke and use the claimed polymers as well as selecting the relative porosity (e.g. open/closed pores) to gain the above advantages and as selection of a material based upon its suitability of intended use.

Allowable Subject Matter

Claims 51,53,88 and 89 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The cited prior art fails to teach a method of laser desorption mass spectrometry where the sample is further modified while on the probe.

Response to Arguments

Applicant's arguments filed 6/28/04 have been fully considered but they are not persuasive.

Applicants' state the new amendments define over the art of record because a rigid and structurally self supporting probe is claimed. Applicants' state the probe of Brodbelt et al. as characterized by Westlake is requires the additional support of a nylon monofilament and DE 3221681 requires a two piece assembly. These arguments are not commensurate in scope with the pending claims. The claim language only requires the probe to be rigid and self supporting which has been met by the cited prior art. The claims do not exclude the probe from comprising several different elements, such as a structurally supporting element. Even if Applicants did include claim language to exclude a multiple piece assembly of the probe, the Office would maintain that unitary construction vs. multi-component assembly would have been within the skill of the art (see In re Larson, 144 USPQ 327).

Applicants state Cerami is directed to a lower resolution method than that presently claimed. These arguments are not commensurate in scope with the pending claims because the pending claims do not distinguish a high or low level of resolution.

Applicants state the rejection of Cerami or Westlake et al. in view of Stuke is not tenable for the reasons each individual rejection above was argued as improper. The Office maintains all of the above rejections are proper and so are the rejections of Cerami or Westlake et al. in view of Stuke

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lyle A Alexander
Primary Examiner
Art Unit 1743